

**REMARKS**

An RCE is being concurrently filed with this Preliminary Amendment. The Commissioner for Patents is hereby authorized by the undersigned to charge the RCE fee and the fee for additional claims over twenty claims and any other required fees to Deposit account number 503814.

The last Office Action has been carefully considered. Applicant would like to thank the Examiner for the interviews graciously granted on June 25 and July 7, 2006. Applicant has added new claims 25-32 which recite the proposed language that the Examiner suggested would define over the cited reference of Key.

**35 USC § 112 Rejections**

Claims 1 and 13 have been amended herein and now are believed to fully comply with 35 USC 112. Claims 1 and 13 now recite in pertinent part that the heat shrink plastic cover forms a seal. It is respectfully submitted that this amendatory language overcomes the 35 USC 112 first and second paragraph rejections. Support for this feature can be found on page 3, bottom paragraph and page 4, lines 5-6 and bottom paragraph. It is therefore respectfully requested that these rejections be withdrawn. In addition, new claims 27 and 28-30 are also believed to recite subject matter not taught or suggested by the Key reference.

**Claim Rejections under 35 US 102 and 35 US 103**  
**As to Key (US 6, 385,878)**

The claimed invention, as recited in independent claims 1 and 13, recites in pertinent part a safety seal system for maintaining alert medications prior to use or administration and a heat-shrink plastic cover, a seal and other distinguishing characteristics on the seal to differentiate a high-alert medication to a person preparing the medical container at point of use or administration to prevent the container from being mistaken for a different container.

In particular, the claimed invention provides a seal formed by a plastic cover that covers a substantial portion of the container and wherein warning statements and other distinguishing characteristics are located on the seal so that in order to remove the seal from the container the preparer is forced to look at the warning statements and other distinguishing characteristics on the seal and thus be alerted to the high alert medication in the container which seal is being opened. The fact that the perforation lines are located on portions of the seal that require the visual attention of the preparer results in the preparer looking at the warning statement and other distinguishing characteristics during the removal of the seal by pulling the seal along the perforated lines and thus alerting the preparer to the high alert medication inside the container.

The patent to Key relates to a tamper-evident labeling system that rotates the label 360 degrees to provide additional product labeling space and at the same time provide a tamper-evident seal in order that consumers can identify if the

contents of the container were altered after the manufacturer produced and sealed the product.

In Key, a standard labeling occurs on the container and not a high alert warning on the seal. Further, since Key is directed toward a rotating label system, the disclosure of Key teaches away from a warning statement that is essentially "in the face" of the preparer when the seal is removed as the label in Keys can rotate rather than being placed in a position where the warning statement is in front of the eyes of the preparer.

Key does not address providing multiple visual, tactile and functional alerts to the provider in the process of medication administration and drawing the provider's special attention to these products at the time the seal is being removed and where the warning alerts are forced to be read by the preparer.

Accordingly, it is respectfully submitted that claims 1 and 13 and the rest of the claims in the present application, for the aforementioned reasons, are not taught or suggested by Key, either alone or in combination with Novacek, et al. It is therefore respectfully requested that the rejections be withdrawn.

New Claims 26 and 32 recite in pertinent part a heat-shrink plastic cover adapted to be placed over an individual high-alert medication container, said heat-shrink plastic cover being tubular, transparent and forming a seal having a warning statement and other distinguishing characteristics on said seal to

differentiate said high-alert medication container to a person preparing said medication container at point of use or administration and to prevent said high alert medication container from being mistaken for a different medication container, said heat shrink plastic cover being configured to substantially cover the container including a portion of the closure of the container and a portion of the closure and having a set of perforation lines configured for a complete removal of the entire heat-shrink plastic cover from the container closure This recited feature is not taught or suggested by the cited prior art of the last office action as noted by the Examiner in his interview summary record.

In view of the amendments and arguments presented herein, and the Examiner's indication of allowable subject matter, it is respectfully requested that the claims remaining in the present application be passed to issue.

Respectfully submitted

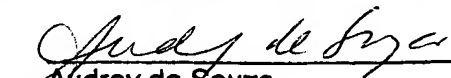
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#### **CERTIFICATE OF MAILING**

I hereby certify that this AMENDMENT is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 13, 2006.

  
Audrey de Souza